Personal Products COMPANY

June 24, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003N-0539, Over-the-Counter Drug Products; Safety and Efficacy Review

Dear Sir or Madam:

Personal Products Company Division of McNeil-PPC, Inc. (PPC) is submitting general comments to the docket regarding the agency's request for data and information, which was published in the December 31, 2003 Federal Register (68 FR 75585 [December 31, 2003]. As the distributor of the K-Y® Brand, PPC has particular interest in patient lubricant and vaginal moisturizer products and appreciates the opportunity for comments.

Summary.
We agree with the FDA that claims to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device such as rectal thermometers, enemas, douches, tampons, and condoms make these products devices. Such products are patient lubricants and are cleared by CDRH. Vaginal moisturizers are not intended to facilitate entry of a diagnostic or therapeutic device.

The content of this submission discusses four points.

- Claims for vaginal moisturizers meet the definition of a cosmetic.
- Vaginal moisturizers are generally not intended to mitigate or treat a disease or affect the structure or function of the body and, therefore, should not be considered by FDA to meet the definition of a drug under 21 USC 321(g).
- Patient lubricants are medical devices.
- FDA has ample regulatory authority.

We will examine each of these subjects in turn.

Claims for vaginal moisturizers meet the definition of a cosmetic.
Section 201(i) of the Food, Drug, and Cosmetic Act defines a cosmetic as follows:

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"The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap."

According the Merriam Webster's Collegiate Dictionary, 10th edition, the term beautify means to "make beautiful or add beauty" and beauty is "the quality or aggregate of qualities in a person or thing that gives pleasure to the senses or pleasurably exalts the mind or spirit." Therefore, claims that relate to "moisturization", "eliminating vaginal dryness that can cause discomfort", and "enhances intimate activity" are aggregate qualities that give pleasure to the senses or pleasurably exalt the mind or spirit, and thus can be broadly interpreted to mean "beautify". These claims, when made for a vaginal lubricant or moisturizer, clearly fall within the statutory definition of a "cosmetic."

Use of vaginal moisturizers does not mitigate or treat a disease or affect the structure or function of the body.

Dryness of the epidermis and epithelium is a common condition, and generally, does not warrant medical attention. Hand and body moisturizers are utilized to relieve dryness and provide comfort. Frequently, skin looks and feels better after use of a moisturizer. These are common products, and their intended use is to moisturize and beautify. Similarly, vaginal dryness is a common condition and not a disease. In general, medical attention is not sought and is not required. Vaginal moisturizers temporarily alleviate dryness. Moisturizers are used to create a barrier to relieve dryness, smooth and soothe; this does not alter the structure or function of the body. Their intended use is to moisturize; therefore, vaginal moisturizers, like hand and body moisturizers, should not be considered drugs within the statutory meaning.

FDA takes the position in its Request for Data that claims "related to relief of discomfort and claims related to the comfort and ease of sexual activity" are drug claims. FDA goes on to state that the specific claims of "with regular use, provides continuous vaginal moisture for most women" and "safe immediate relief of vaginal dryness" are drug claims. FDA, however, provides no guidance on how they reached these conclusions. Certainly, these claims do not demonstrate an intent by the manufacturer to treat or mitigate a disease. FDA must, therefore, believe that these claims somehow demonstrate an intent to affect the structure or function of the body. As noted above, however, we believe that this reasoning is incorrect. It is also inconsistent with FDA's long-held position that topical moisturizers that relieve dry skin, the discomfort of dry skin, or provide long term moisturization are cosmetic claims.

FDA has ample regulatory authority.

In the call for data, "FDA considers claims related to relief of discomfort and claims related to comfort and ease of sexual activity to be drug claims..." If FDA believes that a vaginal moisturizer makes drug claims, the Agency has the authority to take regulatory action against these unlawful claims. This regulatory authority is not limited to cosmetic products. In fact, FDA has used "Warning" letters to inform manufacturers of food, dietary supplements, and cosmetics when the intended use of their products has crossed the line into making illegal drug claims. Therefore, the Agency does not need to create a new regulatory category to ensure regulatory compliance.

The FDA also has ample authority to ensure the safety of cosmetic products by taking action against any cosmetic that is adulterated or misbranded under Sections 601 and 602 of the Act, respectively. Considering these products to be drug products will provide no additional assurances of safety. There is no compelling public health interest that is served by FDA treating these products as drugs.

Patient lubricants are medical devices.
Although in its Request, FDA recognizes the patient lubricants marketed under 21 CFR 880.6375 are regulated by the Agency as medical devices, the FDA "invites the submission of data to support the drug claims" for personal lubricant that "can also have drug claims." PPC agrees that patient lubricants are class I medical devices. However, PPC believes that patient lubricants with "intended uses" not permitted by regulation in 21 CFR 880.6375, may no longer be classified as class I medical devices and under existing medical device regulations require premarket review and clearance by the Agency.

"A patient lubricant is a device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device" (21 CFR 880.6375). Patient lubricants are classified as Class I medical devices. Class I medical devices are considered low risk devices and do not typically require a submission to the FDA prior to their marketing.

The Office of Device Evaluation at Center for Devices and Radiological Health ("CDRH") issued a final guidance ("Guidance") in January 10, 1997 titled, "Deciding When to Submit a 510(k) for a Change to an Existing Device." The purpose of this Guidance was to clarify when a change in a medical device would trigger the requirement that a manufacturer submit a new premarket notification, 510(k), to the Agency. According to this Guidance, any changes to a device that changes its "indication for use" is threshold for contemplating the submission of a 510(k)." Specifically, the question "Does the change affect the indications for use?" is important because, "the general statement of the "Indications for Use" identifies the target population in a significant portion of which sufficient scientific evidence has demonstrated that the device as labeled will provide clinically significant results and at the same time does not present an unreasonable risk of illness or injury associated with the use of the device. Changes in the indications for use section of labeling raise more agency concern than any other aspect of labeling. In fact, most changes in this part of the labeling will require the submission of a 510(k)." Of equal significance is the statement in the Guidance that "Other labeling changes are more frequently recommended for documentation only." Based on this Guidance, labeling changes that do not affect the "indication for use" are unlikely to require Premarket clearance by the Agency, while any claims, including drug claims, that may affect the risk to the target population (presumably due to a new or different intended use) requires review and approval by the Agency.

Patient lubricant products that are marketed as an accessory to a classified device are no longer a class I device and are regulated by the Agency the same as the classified device. For example, a patient lubricant product (class I under 21 CFR 880.6375) that claims "compatible with latex condoms," a class II medical device, will also be classified as a class II medical device and requires premarket notification and clearance by the FDA prior to its marketing. Similarly, when a medical device also makes drug claims, it requires review and clearance by the Agency prior to its marketing. Patient lubricants currently on the market were either in commercial distribution before May 28, 1978, or have been cleared for marketing by Agency. In either case, these products have been previously reviewed and classified by the FDA, and therefore, should not be included in this call for data for a new review.

Conclusion.
The FDA has long held moisturizers to be cosmetic products. Vaginal dryness is not a medical condition and products intended as vaginal moisturizers are cosmetics and do not meet the statutory definition of a drug, because they do not affect the structure or function of the body or mitigate a disease. Under current regulatory framework, the FDA has adequate authority to ensure that cosmetic products do not carry claims that cross the line into drug.

Sincerely,

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